

REMARKS/ARGUMENTS

Claims 1-17 and 21-52 were pending at the time of the mailing of the outstanding Office Action. Claims 1-6, 8, 14-17, 21-34, 41, 51, and 52 are under consideration and claims 7, 9-13, 35-40 and 42-50 are withdrawn from consideration. By this response, claim 1 is amended. One claim has been added. No claims have been cancelled.

In the Office Action of 24 October 2006, the Examiner rejected claims 1, 2, 5, 6, 25, 29 and 30 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over US Pat. No. 5,556,414 to Turi (hereinafter “Turi”). The Examiner rejected claims 4, 8, 22, 23, 27, 29, 32, 34, and 41 under 35 U.S.C. § 103(a) as being unpatentable over Turi. Claims 3, 21, 24, 26, 28, 31, and 33 were rejected under 35 U.S.C. § 103(a) as obvious over Turi in view of US Pat. Pub. No. 2003/0208279 to Atala (hereinafter “Atala”). Claims 14-17 and 51-52 were rejected under 35 U.S.C. § 103(a) as unpatentable over Turi in view of US. Pat. No. 5,680,873 to Berg (hereinafter “Berg”).

The Examiner maintains that Turi discloses a stent for a vessel comprising a tubular body for expansion from a first condition to a second condition, the stent being configured such that a first part of a stent is disposed inwardly relative to a second part of the stent and wherein in the second condition, at least a portion of the first part changes its position relative to the second part such that the at least portion of the first part is not disposed inwardly relative to the second part of the stent wherein the stent consists essentially of human or animal tissue. Alternatively, the Examiner maintains that it would have been obvious for the tissue to be of adequate elasticity.

The Examiner indicates that he considers member 26 of Turi to be a stent inserted inside another stent and indicated that the claims did not preclude this. However, contrary to the Examiner’s parsing of the components of Turi, Turi does not teach or suggest all the elements of claim 1. Turi provides a “composite intraluminal graft.” Turi clearly considers the composite graft to include a vein and a cylindrical-shaped member acting together and secured to each other. (See Abstract, column 5, lines 49-57 and column 6, line 52 - column 7, line 8.) Turi does not consider the vein to be a stent by itself. Nor can

the vein be interpreted as a stent from the disclosure of Turi. By itself, a vein cannot maintain a body passageway in an expanded state. Turi clearly relies on the cylindrical-shaped member to “(prevent) recoil and keep the vein graft tissue in place” and even refers to the cylindrical-shaped member as a “stent” within this system, but not the vein. (Abstract and column 2, lines 57-59.)

Claim 1 patentably distinguishes over Turi because Turi does not teach or suggest a stent that consists essentially of a tubular body that consists essentially of human or animal tissue. As mentioned above, Turi teaches a, “composite intraluminal graft.” For any structure to be described as a “composite,” it must be made of distinct components. (See Webster’s Ninth New Collegiate Dictionary, Merriam-Webster Inc., Springfield, MA, 1984.) Only one portion of Turi’s composite stent, the vein, is described as being of human or animal tissue.

Nevertheless, claim 1 has been amended to further distinguish over Turi and recite that the stent consists essentially of a tubular body and that the tubular body consists essentially of human or animal tissue. Support for this amendment may be found in paragraphs 0013-0016, which indicate that the first wall portion, of human or animal tissue, is combined with wall portions which also comprise a suitable human or animal tissue and that the stent may be produced from body-specific material of the patient to be treated, so that immune responses to the stent are prevented. Additional support may be found in paragraphs 0044-0045.

Therefore, claim 1 patentably distinguishes over Turi which does not teach or suggest a stent consisting essentially of a tubular body, which itself consists essentially of human or animal tissue. Withdrawal of the rejection of claim 1 is respectfully requested.

Claim 1 likewise patentably distinguishes over Atala and Berg. Atala provides a stent in which the stent is merely expanded from a first condition to a second condition with no change in the relative position of a first and a second part of the stent. Berg simply provides a guide catheter. Neither reference teaches or suggests a stent as claimed.

The Applicants continue to object to the Examiner’s characterization of Turi’s disclosure as anticipating the use of a hardening agent in connection with a stent as recited in claims 6 and 30. The Examiner now asserts that the use of a hardening agent is

anticipated by that portion of the adhesive of Turi that hardens the adhesive as it cures or dries. Turi provides no teaching or suggestion in its description of the adhesive that any portion of the adhesive may be said to cause the adhesive to harden as it cures or dries as asserted by the Examiner. Additionally, the common definition of an adhesive, “1: an adhesive substance (as glue or cement)” (Webster’s Ninth New Collegiate Dictionary, Merriam-Webster Inc., Springfield, MA, 1984) fails to provide any suggestion that one component causes the remainder to harden. The Applicants maintain that the Examiner is impermissibly using hindsight to find elements of the present invention in Turi.

It should be noted that the Examiner’s parsing of the components of the Turi adhesive is still contrary to the common definition of an agent, namely “1 a : something that produces or is capable of producing an effect : an active or efficient cause” (Webster’s Ninth New Collegiate Dictionary, Merriam-Webster Inc., Springfield, MA, 1984.) As stated previously, the Applicants, who are also entitled to be their own lexicographers, have described a hardening agent as one that causes or influences another component to harden, consistent with the dictionary definition of an “agent.” As stated previously, while an adhesive can harden as it cures or dries, such a composition would be more properly characterized as a *hardenable* agent (i.e., the agent itself becomes hard) than as a *hardening* agent (i.e., an agent that acts to cause or influence another component to harden). This distinction is clearly described in the specification, where the use of a hardening agent is described in paragraphs 0021–0026, as causing the hardening of the tissue of the stent. In contradistinction, the use of an adhesive is described in paragraphs 0027-0033, which clearly indicates that the adhesive itself is hardened. Each of claims 6 and 30 depend from claims which recite the presence of hardenable tissue. It is further maintained that the recitation of the presence of hardening agents or components thereof in claims, 6, 8, 30 – 34 and 41 is consistent with the transitional phrase “consisting essentially of” in claim 1, because these components do not affect the basic characteristics of the invention as recited in claim 1.

New claim 53 has been added. Claim 53 recites a stent comprising a tubular body adapted to expand from a first condition into a second condition, and an adhesive, and in the second condition, the tubular body is adapted to hold the vessel in an expanded state. The stent comprises a first wall portion comprising at least one human or animal tissue of

adequate elasticity and the adhesive is located in such a way as to maintain the stent in the second condition. While Turi does disclose the use of an adhesive, Turi does not disclose the use of an adhesive that secures the stent in the second (expanded) condition. Instead Turi's use of adhesive is limited to securing the vein to the cylindrical-shaped member in both the unexpanded and expanded states. Therefore, the Applicants maintain that the prior art does not teach or suggest such a stent and that claim 53 is allowable.

Because the cited prior art does not teach or suggest all of the limitations of claims 1-6, 8, 14-17, 21-34, 41, and 51-52, withdrawal of the rejections of these claims under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) is respectfully requested.

The Applicants maintain that generic claims 1-6, 8, 14-17, 21-34, 41, 51, and 52 patentably distinguish over the cited prior art, and therefore request rejoinder of the non-elected claims of group I, claims 7, 9-13, 35-40 and 42-50. The issuance of a Notice of Allowance for claims 1-17 and 21-53 is respectfully solicited.

The outstanding Office action was mailed on 24 October 2006. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for a one month extension of time is hereby made. The Applicants also hereby make a conditional petition for any additional extension of time for response in the event that such a petition is required. The Commissioner is authorized to charge any fee or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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